UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,493	08/21/2003	Eric Rose	50634-BA	9464

7590 12/21/2004

John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,493	ROSE ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9,13,14,19,20,23-28,33 and 34* is/are pending in the application.

4a) Of the above claim(s) *1,13,14,19,20,23-28,33 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 August 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20031124*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1, 13, 14, 19, 20, 23-28, 33, and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 1, 2004.

Applicant's election with traverse of the invention of Group II, claim 9, in the reply filed on November 1, 2004 is acknowledged. The traversal is on the ground(s) that no serious burden would be imposed by examining all of the claims. However, as set forth in the restriction requirement, a serious burden would be imposed upon the examiner because of the additional searching requirements in examining an assay and a therapeutic method. For example, the Lenting et al article applied below underscores the different issues involved in examining products and their methods of use. The Lenting et al article anticipates Applicants' claimed compositions but is insufficient to anticipate or suggest Applicants' claimed therapeutic method because the Lenting et al article does not disclose any in vivo utility for the inactivated Factor IXa. Further searching related to therapeutic methods of use of inactivated Factor IX would be required, and this constitutes an undue burden upon the examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. The drawings are objected to because in Figure 5A, "CaCL" should be "$CaCl_2$". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be

removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

Nucleotide sequences are present at pages 13-14 of the specification which are subject to the sequence disclosure rules, but no sequence listing has been submitted. Further, SEQ ID NOS must be inserted after every sequence subject to the sequence disclosure rules. See 37 CFR 1.821(d).

Applicant must provide an original computer readable form (CRF) copy of the Sequence Listing, an original paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b).

4. The disclosure is objected to because of the following informalities: In the priority claim inserted at page 1, lines 5-10, of the specification, the status of the two U.S. patent applications

should be updated. At page 6, line 21, "congenital" is misspelled. Appropriate correction is required.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by the Benedict et al article (J. Clin. Invest., Vol. 88, pages 1760-1765). The Benedict et al article teaches an aqueous saline solution comprising bovine Factor IXa inactivated with Glu-Gly-Arg-chloromethylketone. The composition is used as a thrombosis inhibitor. See, e.g., the Abstract; page 1760, column 2, first full paragraph; and Table 1.

7. Claim 9 is rejected under 35 U.S.C. 102(a) as being anticipated by the Wong et al abstract (Suppl. I, Circ., Vol. 92, page I-686). The Wong et al abstract teaches a bolus form of dansyl Glu-Gly-Arg chloromethyl ketone-inactivated bovine Factor IXa.

8. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by the Bajaj et al article (PNAS, Vol. 89, pages 152-156). The Bajaj et al article teaches an aqueous composition comprising human Factor IXa inactivated with dansyl Glu-Gly-Arg-chloromethyl ketone. See, e.g., page 153, column 1, first full paragraph. Note with respect to the term "pharmaceutical", an intended use limitation does not impart patentability to product claims which are otherwise

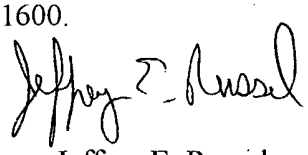
anticipated by the prior art, and the Bajaj et al article teaches every component required to be present by Applicants' claims.

9. Claim 9 is rejected under 35 U.S.C. 102(a) as being anticipated by the Lenting et al article (J. Biol. Chem., Vol. 270, pages 14884-14890). The Lenting et al article teaches an aqueous composition in which human Factor IXaβ, i.e. Factor IXa, is reacted with Glu-Gly-Arg-chloromethyl ketone. See, e.g., page 14884, column 2, second paragraph; page 14885, column 1, last paragraph; and Figure 2. Note with respect to the term "pharmaceutical", an intended use limitation does not impart patentability to product claims which are otherwise anticipated by the prior art, and the Lenting et al article teaches every component required to be present by Applicants' claims.

10. U.S. Patent No. 6,391,300 is cited as art of interest, but does not raise any obviousness-type double patenting issues.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
December 16, 2004